RE: Docket OON-1256

7158 '00 JUL 20 P1:35

E L E C T R O N I C M A I L M E S S A G E

Date: 29-Jun-2000 01:42pm EDT
From: Robert Wolfarth
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Dept:
Tel No:

TO: DELAPR (DELAPR@A1)

Subject: a few thoughts

Robert DeLap, M.D.
FDA/CDER/ORM
Director, Office of Drug Evaluation

Dear Dr. DeLap:

I have a few thoughts to offer pertinent to this week's hearings on possibly increasing availability of medicines to patients as OTC rather than prescription.

I support making more of certain medicines available OTC; however, I understand the safety/efficacy concerns of CDER. Rather than waiting for the drug manufacturer to request the switch, an independent review panel could review the status of the drug after a certain time, maybe after the drug has been in commercial distribution for 5 years. This review panel, comprised of physicians, CDER representatives, and whomever else you deem appropriate, would help eliminate the appearance of financial interests inherent in the current system of letting the manufacturer decide. The panel would only review drugs in certain "mild" categories as specified by CDER. In any case, the manufacturer clearly shouldn't have the only voice in the drug's status.

Though I work in medical regulatory affairs for a U.S. company, I offer these views as a private citizen. I ask that you take these comments into consideration as you gather public opinion.

Thank you for reading my message.

Robert M. Wolfarth
Senior Regulatory Affairs Specialist
Austin, Texas

OON-1256 CH 210

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: JUL 17 2000

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 00N-1256

TO: Dockets Management Branch, HFA-305

☑ The attached material should be placed on public display under the above referenced Docket No.

☐ This material should be cross-referenced to Comment No. _____

Charles J. Ganley, M.D.

Attachment